

REMARKS

Claims 1-24 are pending in the Application.

Claims 1-24 have been rejected.

No claims have been allowed.

Claims 1-3, 5, 7-15, 17-19, and 22-23 have been amended.

Claims 1-24 remain in the Application.

Reconsideration of the claims is respectfully requested.

Amendments to the Specification

The Applicant has amended the specification to correct the spelling of the word “groove” in several places. The Applicant has also amended the Abstract to delete the words “means for” that the Examiner objected to under MPEP § 608.01(b) . The Applicant has also amended the Abstract so that the Abstract contains fewer than one hundred fifty (150) words. No new matter has been added as a result of the these amendments to the specification.

Claim Rejections – 35 U.S.C. § 101

On Page 2 of the December 26, 2002 Office Action, the Examiner rejected Claims 22-24 under 35 U.S.C. § 101 because of the positive recitation of the scleral pocket on Line 14 of Claim 22. The Applicant has amended Claim 22 to replace the word “extends” with the words “is configured

to extend” on Line 14 of Claim 22. The Applicant respectfully submits that this amendment overcomes the rejection of Claims 22-24 under 35 U.S.C. § 101.

35 U.S.C. § 112, Second Paragraph (Definiteness)

On Page 2 of the December 26, 2002 Office Action, the Examiner rejected Claims 8-11, 15-16 and 19 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Applicant has amended Claims 8-11 and Claims 18-19 to delete the word “include” from the two words “include has” in the claims. The Applicant respectfully submits that amended Claims 8-11 and amended Claims 18-19 now have proper syntax and are no longer indefinite.

The Applicant has also amended Claim 15 to restore a portion of text that was inadvertently deleted in a previous amendment. Amended Claim 15 is now reads the same as the originally filed Claim 15. The Applicant respectfully submits that amended Claim 15 (and dependent Claim 16) are no longer indefinite.

The Applicant respectfully submits that these amendments overcomes the rejection of Claims 8-11, 15-16 and 19 under 35 U.S.C. § 112, second paragraph.

Claim Rejections – Obviousness Type Double Patenting

On Pages 2 and 3 of the December 26, 2002 Office Action, the Examiner rejected Claims 1-5, 7, 12-15 and 17 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of (1) United States Patent No. 6,299,640 (the “‘640 Patent”), and (2) United States Patent No. 6,280,468 (the “‘468 Patent”), and (3) United States Patent No. 6,007,578 (the “‘578 Patent”). The ‘640 Patent and the ‘468 Patent and the ‘578 Patent are commonly owned by the assignee of the present Application.

The Applicant is concurrently submitting a Terminal Disclaimer under 37 C.F.R. § 1.321, disclaiming any portion of the term of a patent issuing on the present Application that exceeds the terminal date of the ‘640 Patent, the ‘468 Patent, and the ‘578 Patent.

The Applicant now respectfully requests the Examiner to withdraw the obviousness-type double patenting rejection as moot. In submitting the Terminal Disclaimer, the Applicant makes no admission regarding the merits of the now moot obviousness-type double patenting rejection.

The Applicant respectfully submits that the Terminal Disclaimer overcomes the rejection of Claims 1-5, 7, 12-15 and 17 under the doctrine of obviousness-type double patenting.

35 U.S.C. § 102 (Anticipation)

Claims 1-7 and 12-17 were rejected under 35 U.S.C. § 102(b) as being anticipated by United States Patent No. 5,354,331 to *Schachar*. These rejections are respectfully traversed.

It is axiomatic that a prior art reference anticipates the claimed invention under 35 U.S.C. § 102 only if every element of a claimed invention is identically shown in that single reference, arranged as they are in the claims. MPEP § 2131; *See, In re King*, 231 U.S.P.Q. 136, 138 (Fed. Cir. 1986) (citing with approval, *Lindemann Maschinenfabrik v. American Hoist and Derrick*, 221 U.S.P.Q. 481, 485 (Fed. Cir. 1984)); *In re Bond*, 910 F.2d 831, 832, 15 U.S.P.Q.2d 1566, 1567 (Fed. Cir. 1990). Anticipation is only shown where each and every limitation of the claimed invention is found in a single prior art reference. MPEP § 2131; *In re Donohue*, 766 F.2d 531, 534, 226 U.S.P.Q. 619, 621 (Fed. Cir. 1985).

With respect to any of Claims 1-7 and 12-17, a determination of anticipation in accordance with Section 102 requires that each feature claimed therein be described in sufficient detail in *Schachar* to enable one of ordinary skill in the art to make and practice the claimed invention.

The Applicants respectfully disagree with the Examiner's assertions regarding the subject matter disclosed in the *Schachar* reference. The Applicant respectfully submits that the *Schachar* reference does not show each and every limitation of the Applicant's invention. The Applicant directs the Examiner's attention to Claim 1, which contains unique and novel limitations:

1. (Original) A prosthesis adapted for contact with the sclera of an eyeball, said prosthesis comprising a body having a first end and a second end, said body having a planform adapted to expand said contacted sclera to increase the effective working distance of the ciliary muscle of the eyeball. (Emphasis added).

The scleral expansion band described in the *Schachar* reference does not comprise a body having a first end and a second end of the type described and claimed in the present Application. The scleral expansion band has the form of a continuous ring. There is no first end and there is no second end of the scleral expansion band described in the *Schachar* reference. Therefore, the *Schachar* reference does not anticipate Claims 1-7 and 12-17.

The Examiner stated that “Some of the disclosed embodiments are elongated with first and second ends, as seen from column 7, lines 1-12; column 8, lines 22-26; etc.” (December 26, 2003 Office Action, Page 4, Lines 7-8). The Applicant respectfully disagrees with the Examiner’s characterization of the *Schachar* reference as teaching embodiments that are “elongated with first and second ends.” *Schachar* states: “The scleral expansion band may also be made in a plurality of parts that can be assembled prior to use or may be installed separately to form a complete band.” (*Schachar*, Column 7, Lines 1-3). It is clear that the “plurality of parts” are assembled to form a “complete band.” There is no teaching or suggestion of using the individual parts of the complete scleral expansion band separately (i.e., not formed into a complete ring). On the contrary, the individual parts of the scleral expansion band are always assembled into a complete band. The assembly of the parts may be “prior to use” (i.e., after the parts are assembled into a complete

band, then the complete band is inserted into the sclera of the eye). Alternatively, the parts may be “installed separately” (i.e., connected to each other one at a time within the eye) “to form a complete band” within the sclera of the eye. In either case, the individual parts of the scleral expansion band are never used separately. They are always used in a complete, unitary scleral expansion band has the form of a continuous ring.

The Examiner also stated “Regarding claim 2 and others: column 7, lines 36-42.” (December 26, 2002 Office Action, Page 4, Lines 11-12). The portion of *Schachar* cited by the Examiner also refers to a complete band structure and not to embodiments that are “elongated with first and second ends.” “It is also possible to expand the sclera in the region of the ciliary body by positioning a band within or just inside the sclera, the band having a diameter just greater than the natural diameter of the overlying tissue.” (*Schachar*, Column 7, Lines 26-29) (Emphasis added). The Examiner also objected to the recitation of elements in the claims that are “adapted to” perform a function. The language “adapted to” was said to not provide a positive limitation in the claims. The Applicant has amended Claims 1-3, 5, 7, 12-15, 17 and 22 to delete the phrase “adapted to.”

For the reasons stated above, the Applicant respectfully submits that the *Schachar* reference does not anticipate the unique and novel elements of the Applicant’s invention. Therefore, the rejection of Claims 1-7 and 12-17 under 35 U.S.C. § 102(b) has been overcome.

35 U.S.C. § 103 (Obviousness)

Claims 8-11 and 18-21 were rejected under 35 U.S.C. § 103(a) as being unpatentable over United States Patent No. 5,354,331 to *Schachar*. This rejection is respectfully traversed.

During *ex parte* examinations of patent applications, the Patent Office bears the burden of establishing a *prima facie* case of obviousness. MPEP § 2142; *In re Fritch*, 972 F.2d 1260, 1262, 23 U.S.P.Q.2d 1780, 1783 (Fed. Cir. 1992). The initial burden of establishing a *prima facie* basis to deny patentability to a claimed invention is always upon the Patent Office. MPEP § 2142; *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992); *In re Piasecki*, 745 F.2d 1468, 1472, 223 U.S.P.Q. 785, 788 (Fed. Cir. 1984). Only when a *prima facie* case of obviousness is established does the burden shift to the applicant to produce evidence of non-obviousness. MPEP § 2142; *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992); *In re Rijckaert*, 9 F.3d 1531, 1532, 28 U.S.P.Q.2d 1955, 1956 (Fed. Cir. 1993). If the Patent Office does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of a patent. *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992); *In re Grabiak*, 769 F.2d 729, 733, 226 U.S.P.Q. 870, 873 (Fed. Cir. 1985).

A *prima facie* case of obviousness is established when the teachings of the prior art itself suggest the claimed subject matter to a person of ordinary skill in the art. *In re Bell*, 991 F.2d 781, 783, 26 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1993). To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the

references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed invention and the reasonable expectation of success must both be found in the prior art, and not be based on an applicant's disclosure. MPEP § 2142.

Applicants respectfully submit that the Patent Office has not established a *prima facie* case of obviousness with respect to the Applicants' invention. The Applicants direct the Examiner's attention to amended Claim 8 which shows novel and unique features:

8. (Currently amended) The prosthesis set forth in Claim 7 wherein said at least one of said first end and said second end has a partially concave top surface. (Emphasis added).

The Examiner stated that "Complementary concave and convex surfaces at the ends of the band would have been obvious in order that the overlapping 'ends may slide past one another' (column 7, lines 6-7) and '[t]he length of the overlap may be adjusted' (column 7, line 8-9) while maintaining a ring-like shape (via the tracking of the engaging concave and convex surfaces) and a substantially uniform thickness throughout." (December 26, 2002 Office Action, Page 4, Lines 14-18). The Applicant respectfully disagrees with the Examiner's characterization of the *Schachar* reference as teaching "complementary concave and convex surfaces at the ends of the band." The *Schachar* reference does not mention, suggest or even hint at the use of (1) concave surfaces,

or (2) convex surfaces, or (3) complementary concave and convex surfaces. The *Schachar* reference does mention using a scleral expansion band that is adjustable in circumference. “For example, the band may be formed from a strip of material, e.g., metal or synthetic resin, with overlapping ends so that the ends may slide past one another thereby adjusting the circumference of the band.” (*Schachar*, Column 7, Lines 3-7). But there is no mention of concave or convex surfaces.

The Applicant respectfully asserts that the Examiner has inappropriately applied hindsight when combining the teachings of the *Schachar* reference and the concept of using concave or convex surfaces in a scleral prosthesis in order to arrive at the claimed invention recited in Claims 8-11 and 18-21. The teaching of using concave or convex surfaces in a scleral prosthesis comes from the Applicant’s patent application. Therefore, the Applicant respectfully submits that the rejection of Claims 8-11 and 18-21 under 35 U.S.C. §103(a) should be withdrawn.

Further, even if the concept of concave and convex surfaces could be properly combined with the *Schachar* reference, the combination would still not teach, suggest or hint at the Applicant’s invention. Even if complementary concave and convex surfaces were used in the overlapping ends of the individual portions of the *Schachar* scleral expansion band, there is no teaching in *Schachar* to use the individual portions separately. They would always be used in a complete band.

For the reasons stated above, the Applicant respectfully submits that the *Schachar* reference does not render obvious the unique and novel elements of the Applicant’s invention. Therefore, the rejection of Claims 8-11 and 18-21 under 35 U.S.C. § 103(a) has been overcome.

The Applicant's attorney made the arguments set forth above to place this Application in condition for allowance. In the alternative, the Applicant's attorney is making the arguments to properly frame the issues for appeal. In making these arguments, the Applicant makes no admission concerning any now moot rejection or objection, and affirmatively denies any statement or averment by the Examiner that was not specifically addressed herein.

SUMMARY

If any issues arise, or if the Examiner has any suggestions for expediting allowance of this Application, the Applicant respectfully invites the Examiner to contact the undersigned at the telephone number indicated below or at wmunck@davismunck.com. The Commissioner is hereby authorized to charge any additional fees connected with this communication or credit any overpayment to Deposit Account No. 50-0208.

Respectfully submitted,

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